

DATE OUT: 25/ FEB / 2004

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]**
DP BARCODE No.: D295705 **File Symbol No.:** 73510-L
PRODUCT NAME: Marketquest One Drop Flea & Tick Control with IGR
COMPANY: Marketquest Incorporation
FOOD USE [] INTEGRATED FORMULATION []
PCC: 105402, 109701; **Decision No.** 331701

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2/25/04
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INTRODUCTION:

The registrant has submitted product chemistry data in support of the registration application for the proposed end-use product. The product chemistry data have been submitted under MRID No. 460876-01. The registrant has submitted a CSF for basic formulation (dated 7-17-03) and two CSF's for alternate formulations # 1 & # 2 (both dated 7-17-03). The registrant is citing storage stability and corrosion characteristics data done on a very similar product with Reg. No. 73510-2 (which does not contain methoprene as AI). TRB has been asked to evaluate product chemistry data submitted for the proposed product.

SUMMARY OF FINDINGS

1. The proposed product contains Permanone Technical (Reg. No. 73049-379, 92% Permethrin), and MCSI S-Methoprene Concentrate (Reg. No. 70062-3, 99.0%) as the active ingredients with product label claims of 45% and 1.2% respectively.

***Product ingredient source information
may be entitled to confidential treatment***

Alternate sources for active ingredient Permethrin:

CSF Alt # 1, Reg. No. [REDACTED] CSF Alt # 2, Reg. No. [REDACTED]

2. The CSF's for the basic and alternate formulations (all dated 7-17-03) are filled out correctly and completely. The nominal concentrations of the active ingredients concur with the product label claim nominal concentrations. The CSF's are in compliance with PR Notice 91-2. The CSF's for alternate formulations are in compliance with 40CFR§152.43. All the inert ingredients used in the formulation are cleared by the Agency. The registrant has proposed expanded certified limits in case of one of the inert ingredient [REDACTED]. The data submitted corresponding to the guideline reference 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively. [MRID No. 460876-01]

3. The data submitted corresponding to the guideline reference 830.1600 (description of materials used to produce the product) and 830.1650 (description of formulation process) satisfy the data requirement 40§CFR158.160 and 158.165 respectively. [MRID No. 460876-01]

4. The data submitted corresponding to guideline reference 830.1670 (discussion on the formation of impurities) satisfy the data requirements of and 40CFR§158.167. [MRID No. 460876-01]

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5. The data submitted corresponding to the guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The active ingredients were determined simultaneously by HPLC / UV detector (224 nm from 0 to 13 minutes & 263 nm from 13.01 min to the end of the run). [MRID No. 460876-01]

6. The data submitted corresponding to 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190, except for storage stability (830.6317) and corrosion characteristics (830.6320). [MRID No. 460876-01]

7. The registrant has cited the data for storage stability (830.6317) and corrosion characteristics (830.6320) from the registered product with Reg. No. 73510-2 (MRID No. 455570-01). The only difference in the two products is that the proposed product contains 1.2% Methoprene as the active ingredient and it is expected that the presence of small amounts of methoprene will not make significant change in the results of one year storage and corrosion studies.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable.
2. The CSF's for basic and alternate formulations (all dated 07-17-03) are acceptable with comments.

Comments: The proposed expanded certified limits for one inert ingredient (which is being used as the [REDACTED] in the formulations) must be justified.

3. The product chemistry data submitted corresponding 830 Series Subgroup B (physical/chemical properties), including the cited data on one year storage stability (830.6317) and corrosion characteristics (830.6320) are acceptable. The registrant is advised to perform accelerated storage and corrosion study on the proposed product (two weeks at 54°C) to confirm the statement in item # 7 above.

4. Since the Flash point of the proposed product is 129°F, in compliance with 40CFR§156.78, the warning language under Physical or Chemical Hazards of the product label must be changed to:

"Combustible. Do not use or store near heat or open flame"

Product ingredient source information may be entitled to confidential treatment

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PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic & Alternate CSF's)	Y	07-17-03
830.1600. Beginning Materials	Y	460876-01
830.1650. Formulation Process	Y	" " "
830.1670. Discussion of Impurities	Y	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (Basic & alternate CSF's)	Y	07-17-03
830.1800. Enforcement Analytical Method	Y	460876-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	NA		
830.6303. Physical State	Y	Liquid	460876-01
830.6304. Odor	NA		
830.6314. Oxidation/Reduction Action	Y	None	460876-01
830.6315. Flammability	Y	129°F	" " "
830.6316. Explodability	Y	Non-explosive	" " "
830.6317. Storage stability	Y (cited)	stable	455570-01
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	Y (cited)	non-corrosive	455570-01
830.6321. Dielec. Bkd. Vltg.	NA		
830.7000. pH	NA	non-ionic solution	460876-01
830.7100. Viscosity	Y	100 cps	" " "
830.7000. Density/Bulk Density	Y	1.033-1.141 g/ml	" " "

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

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Enforcement analytical method: (MRID No. 460876-01)

The active ingredients in the proposed product were assayed by LC/UV method).

Equipment and Parameters

HPLC: HPLC machine equipped with a Kontron LCT 414 HPLC Pump, autosampler and injector, Kontron 432 UV detector, and Spectr Physics Integrator.

Column: Lichrospher C18 reverse phase 250 mm x 5 mm

Eluent: Acetonitrile : Water (80:20)

Flow rate: 2.0 ml/min

Detector: UV (224 nm from 0 to 13 min changed to 263 nm from 13.01 min to the end of the run).

Column pressure: 100 - 200 bar

Injection volume: full loop 20 µL

Typical retention time: Permethrin cis isomer - 12 minutes; Permethrin trans isomer - 10 minutes
3-Phenoxybenzyl alcohol - 2 minutes

The method was validated for linearity, accuracy and precision.